AUG - 5 2004 K041721

9. 510(k) Summary

Company:	HOYA ConBio (formerly Continuum Electro-Optics, Inc.) 47733 Fremont Blvd Fremont, CA 94538 (800) 532-1064 phone (510) 445-4550 fax
Contact:	Jim Green Vice President of Engineering
Device Trade Name:	LVI lase
Common Name:	Dental diode laser
Classification Name: Classification Code:	Instrument, surgical, powered, laser 79-GEX
Equivalent Device(s):	DioDent Dental Laser System by HOYA ConBio, Aurora by Premier Laser System, Twilite or Dentek LD-15 Diode Laser System by BioLase Technologies, DioLase ST by American Medical Technology (formerly ADT)
Intended Use:	The LVI lase is intended for incision, excision, ablation, vaporization, and/or coagulation of oral soft tissue (including marginal and interdental gingival and epithelial lining of free gingiva). It is also intended for light activation for bleaching materials for teeth whitening, and laser-assisted bleaching/whitening for teeth whitening.
Comparison:	The LVI lase, the DioDent Dental Laser System, the Aurora Diode Laser System, the Twilite/Dentek LD-15, the Dental Diode Laser, and the DioLase ST are equivalent in operating parameters, physical characteristics, and intended uses. (NOTE: Of the equivalent devices mentioned here, only the DioDent and the Twilite are cleared for teeth whitening intended uses. The LVI lase is seeking clearance for this in this submission).
Nonclinical Performance Data:	None
Clinical Performance Data:	None
Additional Information:	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 5 2004

Mr. Jim Green
Vice President of Engineering
HOYA ConBio
47733 Fremont Boulevard
Fremont, California 94538

Re: K041721
Trade/Device Name: LVI Lase
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 21, 2004
Received: June 29, 2004

Dear Mr. Green:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1. Indications for Use Statement

510(k) Number: K041721

Device Name: LVI lase

Indications for Use: For the incision, excision, ablation, vaporization, and hemostasis of oral soft tissue.
Examples:
Excisional and incisional biopsies
Exposure of unerupted teeth
Fibroma removal
Frenectomy and frenotomy
Gingival troughing for crown impressions
Gingivectomy
Gingivoplasty
Gingival incision and excision
Hemostasis
Implant recovery
Incision and drainage of abscess
Leukoplakia
Operculectomy
Oral papillectomies
Pulpotomy
Pulpotomy as an adjunct to root canal therapy
Reduction of gingival hypertrophy
Reduction of bacterial level (decontamination) and inflammation
Soft tissue crown lengthening
Sucular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)
Treatment of aphthous ulcers
Vestibuloplasty
Biopsy incision and excision
Lesion (tumor) removal

For light activation for bleaching materials for teeth whitening
For laser-assisted bleaching/whitening for teeth.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041721

Prescription Use ____X____ OR Over-the-Counter Use_____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)